

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		10517509
	Filing Date		2005-06-13
	First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.	
	Art Unit	1614	
	Examiner Name	Samira Jean-Louis	
	Attorney Docket Number	0470-045922	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6500814		2002-12-31	Hesch	
	2	6214815		2001-04-10	Shangold et al.	
	3	5827843		1998-10-27	Koninckx	
	4	5662927		1997-09-02	Ehrlich et al.	
	5	5633242		1997-05-27	Oettel et al.	
	6	5468736		1995-11-21	Hodgen	
	7	5340586		1994-08-23	Pike et al.	
	8	5340585		1994-08-23	Pike et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10517509
Filing Date		2005-06-13
First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.	
Art Unit	1614	
Examiner Name	Samira Jean-Louis	
Attorney Docket Number	0470-045922	

9	5340584		1994-08-23	Spicer et al.	
10	5223261		1993-06-29	Nelson et al.	
11	5130137		1992-07-14	Crowley, Jr.	
12	4937238		1990-06-26	Lemon	
13	4762717		1988-08-09	Crowley, Jr.	
14	4722941		1988-02-02	Eckert et al.	
15	4624665		1986-11-25	Nuwayser	
16	4573996		1986-03-04	Kwiatek et al.	
17	4460372		1984-07-17	Campbell et al.	
18	3797494		1974-03-19	Zaffaroni	
19	3440320		1969-04-22	Sackler et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	10517509
Filing Date	2005-06-13
First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.
Art Unit	1614
Examiner Name	Samira Jean-Louis
Attorney Docket Number	0470-045922

If you wish to add additional U.S. Patent citation information please click the Add button. [Add](#)

U.S.PATENT APPLICATION PUBLICATIONS [Remove](#)

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020183299		2002-12-05	Voskuhl	

If you wish to add additional U.S. Published Application citation information please click the Add button. [Add](#)

FOREIGN PATENT DOCUMENTS [Remove](#)

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
/S.J.L./	1	0185154	WO	A2	2001-11-15	Oregon Heath Sciences University et al.		<input type="checkbox"/>
/S.J.L./	2	1700602	EP	A1	2001-05-18	Pantarhei Bioscience B.V		<input type="checkbox"/>
/S.J.L./	3	0130357	WO	A	2001-05-03	Theramex		<input type="checkbox"/>
/S.J.L./	4	0073416	WO	A1	2000-12-07	University of Cincinnati		<input type="checkbox"/>
/S.J.L./	5	19917930	DE	A1	2000-10-19	Schering		<input type="checkbox"/>
/S.J.L./	6	9858657	WO	A1	1998-12-30	Mannaerts et al		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10517509
Filing Date		2005-06-13
First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.	
Art Unit	1614	
Examiner Name	Samira Jean-Louis	
Attorney Docket Number	0470-045922	

/S.J.L./	7	9603929	WO	A1	1996-02-15	Biex, Inc.		<input type="checkbox"/>
/S.J.L./	8	9517895	WO		1995-07-06	Ehrlich et al.		<input type="checkbox"/>
/S.J.L./	9	9502408	WO	A1	1995-01-26	Schering		<input type="checkbox"/>
/S.J.L./	10	9426207	WO		1994-11-24	University of Southern California		<input type="checkbox"/>
/S.J.L./	11	9218107	WO	A1	1992-10-29	University of Southern California		<input type="checkbox"/>
/S.J.L./	12	468690	EP	A1	1991-07-17	Sumitomo Chemical Co., Ltd.		<input type="checkbox"/>
/S.J.L./	13	0402950	EP	A1	1975-12-18	Orion Yhtymae OY		<input type="checkbox"/>
/S.J.L./	14	2426779	DE	A1	1975-12-18	Schering AG		<input type="checkbox"/>
/S.J.L./	15	2336434	DE	A1	1975-04-17	Schering AG		<input type="checkbox"/>
/S.J.L./	16	2336433	DE	A1	1975-04-03	Schering AG		<input type="checkbox"/>
/S.J.L./	17	9603929	WO	A1	1966-02-15			<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10517509
Filing Date	2005-06-13
First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.
Art Unit	1614
Examiner Name	Samira Jean-Louis
Attorney Docket Number	0470-045922

If you wish to add additional Foreign Patent Document citation information please click the Add button [Add](#)

NON-PATENT LITERATURE DOCUMENTS

[Remove](#)

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
/S.J.L./	1	VISSER et al., "In vitro effects of estetrol on receptor binding, drug targets and human liver cell metabolism," CLIMACTERIC (2008) 11(1) Appx. II: 1-5.	<input type="checkbox"/>
/S.J.L./	2	VISSER et al., "First human exposure to exogenous single-dose oral estetrol in early postmenopausal women," CLIMACTERIC (2008) 11(1): 1-10.	<input type="checkbox"/>
/S.J.L./	3	VISSER et al., "Clinical applications of estetrol," J. Of Steroid Biochem and Molecular Biol. (2009) 114: 85-89.	<input type="checkbox"/>
/S.J.L./	4	HOLINKA et al., "Estetrol: A unique steroid in human pregnancy," J. of Steroid Biochem and Molecular Biol. (2009) 110: 138-143.	<input type="checkbox"/>
/S.J.L./	5	COELINGH BENNINK et al., "Oral bioavailability and bone sparing effects of estetrol in an osteoporosis model," CLIMACTERIC (2008) 11 (Supp 3): 1-13.	<input type="checkbox"/>
/S.J.L./	6	ALBERTAZZI PAOLA et al., "The Effect of Tibolone Versus Continuous Combined Norethisterone Acetate and Oestradiol on Memory, Libido and Mood of Postmenopausal Women: A Pilot study"; Database Biosis 'Online'; 10/31/2000; pages 223-229; Vol. 36, No. 3; Biosciences Information Service, Philadelphia, PA., U.S.	<input type="checkbox"/>
/S.J.L./	7	ALLEN ET AL., An Ovarian Hormone: Preliminary Report on Its Localization, Extraction and Partial Purification, and Action in Test Animals, JAMA, September 8, 1923, Vol. 81, pp. 819-821.	<input type="checkbox"/>
/S.J.L./	8	ALLEN ET AL., The Induction of a Sexually Mature Condition in Immature Females by Injection of the Ovarian Follicular Hormone, Am. J. Physiol., 1924, Vol. 69, pp. 577-588.	<input type="checkbox"/>
/S.J.L./	9	JONES ET AL., The Effects of Various Steroids on the Vaginal Histology in the Rat, Fertility and Sterility, April 1973, Vol. 24, No. 4, pp. 284-291.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10517509
Filing Date		2005-06-13
First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.	
Art Unit	1614	
Examiner Name	Samira Jean-Louis	
Attorney Docket Number	0470-045922	

/S.J.L./	10	TULCHINSKY ET AL., Plasma Esterol as an Index of Fetal Well-Being, J. Clin. Endocrinol. Metab., 1975, Vol 40. Pp. 560-567.	<input type="checkbox"/>
/S.J.L./	11	JOZAN ET AL., Different Effects of Oestradiol, Oestriol, Oestrol and of Oestrone on Human Breast Cancer Cells (MCF-7) in Long Term Tissue Culture, Acta Endocrinologica, 1981, Vol. 98, pp. 73-80.	<input type="checkbox"/>
/S.J.L./	12	HAMMOND ET AL., A Versatile Method for the Determination of Serum Cortisol Binding Globulin and Sex Hormone Binding Globulin Binding Capacities, 1983, Vol. 132, pp. 101-110.	<input type="checkbox"/>
/S.J.L./	13	ELGER ET AL., Sulfamates of Various Estrogens are Prodrugs with Increased Systemic and Reduced Hepatic Estrogenicity at Oral Application, J. Steroid Biochem. Molec. Biol., 1995, Vol. 55, No. 3 / 4, pp. 395-403.	<input type="checkbox"/>
/S.J.L./	14	MURPHY ET AL., Endometrial Effects of Long-Term Low-Dose Administration of RU486, Fertility and Sterility, April 1995, Vol. 63, No. 4, pp. 761-766.	<input type="checkbox"/>
/S.J.L./	15	REEL ET AL., Survey and Assessment of Mammalian Estrogen Biological Assays for Hazard Characterization, Fundamental and Applied Toxicology, 1996, Vol. 34, pp. 288-305.	<input type="checkbox"/>
/S.J.L./	16	BERAL ET AL., Use of HRT and the Subsequent Risk of Cancer, Journal of Epidemiology and Biostatistics, 1999, Vol. 4, No. 3, pp. 191-215.	<input type="checkbox"/>
/S.J.L./	17	TAVANI ET AL., The Adverse Effects of Hormone Replacement Therapy, Drugs & Aging, May 1999, Vol. 14, No. 5, pp. 347-357.	<input type="checkbox"/>
/S.J.L./	18	PIKE ET AL., Progestins and Menopause: Epidemiological Studies of Risks of Endometrial and Breast Cancer, Steroids, 2000, Vol. 65, pp. 359-664.	<input type="checkbox"/>
/S.J.L./	19	AVVAKUMOV ET AL., Steroid-binding Specificity of Human Sex Hormon-binding Globulin Is Influenced by Occupancy of a Zinc-binding Site, The Journal of Biological Chemistry, August 25, 2000, Vol. 275, No. 34, pp. 25920-25925.	<input type="checkbox"/>
/S.J.L./	20	HOLINKA ET AL., "In Vivo Effects of Esterol on the Immature Rat Uterus", Biology of Reproduction, Society for the Reproduction Society for the Study of Reproduction, Champaign, IL, US, March 1979 (1979-03), Vol. 20, No. 2, pp. 242-246.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10517509
Filing Date	2005-06-13
First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.
Art Unit	1614
Examiner Name	Samira Jean-Louis
Attorney Docket Number	0470-045922

/S.J.L./	21	HOLINKA, ET AL., "Comparison of Effects of Esterol and Tamoxifen with Those of Estriol and Estradiol on the Immature Rat Uterus", Biology of Reproduction, Society for the Reproduction Society for the Study of Reproduction, Champaign, IL, US, 1980, Vol. 22, No. 4, pp. 913-926.	<input type="checkbox"/>
/S.J.L./	22	JANSSON ET AL., "Estrogen Induces a Potent Suppression of Experimental Autoimmune Encephalomyelitis and Collagen-Induced Arthritis in Mice", Journal of Neuroimmunology, Elsevier Science Publishers BV XX, 1994, Vol. 53, No. 2, pp. 203-207.	<input type="checkbox"/>
Not provided	23	ERDBRUEGGER ET AL., Drug Discovery Today: Disease Mechanisms (2004), Vol. 1, pp. 73-81.	<input type="checkbox"/>
/S.J.L./	24	Lab Tests Online (www.labtestsonline.org/understanding/conditions/autoimmune.html) retrieved on 10/15/2009.	<input type="checkbox"/>
/S.J.L./	25	www.tiscali.co.uk/lifestyle/healthfitness/health_advice/netdoctor/archive/000489.html, retrieved on 10/15/2009.	<input type="checkbox"/>
/S.J.L./	26	MedlinePlus Medical Encyclopedia: Multiple Sclerosis, retrieved on 03/28/2008 via www.nlm.nih.gov/medlineplus/ency/article/000737.htm, dated on 08/06/2007, Page 1 and 2; also see WebMD: Multiple Sclerosis - Prevention, retrieved on 03/28/2008 via www.webmd.com/multiple-sclerosis/tc/multiple-sclerosis-ms-prevention, dated on 03/23/2006.	<input type="checkbox"/>
/S.J.L./	27	MedlinePlus Medical Encyclopedia: rheumatoid arthritis, retrieved on 03/28/2008 via www.nlm.nih.gov/medlineplus/ency/article/000431.htm, dated on 07/27/2007, page 1-2 and 4; also WebMD: Rheumatoid Arthritis - Prevention, retrieved on 03/28/2008 via www.webmd.com/rheumatoid-arthritis/tc/rheumatoid-arthritis-prevention, dated on 08/23/2006.	<input type="checkbox"/>
/S.J.L./	28	TSENG et al., "Heterogeneity of Saturable Estradiol Binding Sites in Nuclei of Human Endometrium. Estetrol Studies", (1978), Vol. 9, pp 1145-1148.	<input type="checkbox"/>
/S.J.L./	29	FISHMAN et al., "Fate of 15 α -Hydroxyestriol-3H in Adult Man", J. Clin. Endocrinol. Metab., (1970), Vol. 31, pp 436-438.	<input type="checkbox"/>
/S.J.L./	30	LEVINE et al., "Uterine vascular effects of estetrol in nonpregnant ewes", Am. J. Obstet. Gynecol., (1984), [148], Vol. 73, pp 735-738.	<input type="checkbox"/>
/S.J.L./	31	MARTUCCI et al., "Direction of Estradiol Metabolism as a Control of its Hormonal Action - Uterotrophic Activity of Estradiol Metabolites", Endocrin., (1977), Vol. 101, pp 1709-1715.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10517509
Filing Date		2005-06-13
First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.	
Art Unit	1614	
Examiner Name	Samira Jean-Louis	
Attorney Docket Number	0470-045922	

/S.J.L./	32	MARTUCCI et al., "Uterine Estrogen Receptor Binding of Catecholestrogens and of Estetrol (1,3,5(10)-Estratriene-3, 15a, 16a, 17 β -Tetrol)", Steroids, (1976), Vol. 27, pp 325-333.	<input type="checkbox"/>
/S.J.L./	33	SEEGER et al., "The inhibitory effect of endogenous estrogen metabolies on copper-mediated in vitro oxidation of LDL", Int. Journal of Clinical Pharmacology and Therapeutics, (1998), Vol. 36, No. 7, pp 383-385.	<input type="checkbox"/>
/S.J.L./	34	TSENG et al., "Competition of Estetrol and Ethynylestradiol with Estradiol for Nuclear Binding in Human Endometrium", Journal of Steroid Biochemistry, (1976), Vol. 7, pp 817-822.	<input type="checkbox"/>
/S.J.L./	35	KUIPERS ET AL., "Enterohepatic Circulation in the Rat", Gastroenterol., Vol. 88, pp 403-411 (1985).	<input type="checkbox"/>
/S.J.L./	36	SCHWARTZ, "A Model for the Regulation of Ovulation in the Rat", Recent Prog. Horm. Res., Vol. 25, pp 1-55, (1969).	<input type="checkbox"/>
/S.J.L./	37	BEATTIE ET AL., "The Differential Effects of Diestrous Progestogen Administration on Proestrous Gonadotrophin Levels, Endocrinol", Vol 97, pp. 885-890, (1975).	<input type="checkbox"/>
/S.J.L./	38	DE VISSER ET AL., "Endocrinological Studies with (7a, 17 a)-17-Hydroxy-7-me norpregn-5(10)-en-20-yn-3-one (Org OD 14), Arzneim, Forsh., Vol. 34, pp 1010-1020, (1984).	<input type="checkbox"/>
/S.J.L./	39	National Cancer Institute: Breast cancer prevention retrieved online 08/07/2007 from the internet; http://www.cancer.gov/templates/doc.aspx?viewed+D972A74B-D25A-4F86-B8ED-33EB3C0450E4&version, page 1 .	<input type="checkbox"/>
/S.J.L./	40	Medline Plus: Medical Encyclopedia: Ovarian cancer retrieved online on 08/09/2007 from the internet: https://www.nlm.nih.gov/medlineplus/ovariancancer.html , page 1 dated 07/31/2007.	<input type="checkbox"/>
/S.J.L./	41	COELINGH-BENNINK ET AL., "Estetrol review: profile and potential clinical applications", International Menopause Society, CLIMATERIC, Vol. 11, (Suppl 1), pp. 47-58 (2008).	<input type="checkbox"/>
/S.J.L./	42	SPEROFF ET AL., Clinical Gynecologic Endocrinology and Infertility, Seventh Edition, page 270 (partial).	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10517509
Filing Date	2005-06-13
First Named Inventor	Herman Jan Tijmen Coelingh Bennink et al.
Art Unit	1614
Examiner Name	Samira Jean-Louis
Attorney Docket Number	0470-045922

/S.J.L./	43	WHITE ET AL., "The pharmacokinetics of Intravenous Estradiol: A Preliminary Study", Pharmacotherapy, Vol. 18, pp. 1343-1346, (1998) (Abstract).	<input type="checkbox"/>
/S.J.L./	44	HAMMOND ET AL., "Estetrol does not bind sex hormone binding globulin or increase its production by human HepG2 cells", International Menopause Society, CLIMATERIC, Vol, 11, (Suppl. 1), pp. 41-46, (2008).	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	/Samira Jean-louis/	Date Considered	03/27/2010
--------------------	---------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.